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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,688	07/27/2006	Charalabos Pothoulakis	1440.2034-003	2207
21005 7590 08/20/2008 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				
EXAMINER LANDSMAN, ROBERT S				
ART UNIT		PAPER NUMBER		
1647				
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08/20/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/549,688

**Applicant(s)**

POTHOULAKIS ET AL.

**Examiner**

ROBERT LANDSMAN

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-13 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 6/19/08

## DETAILED ACTION

### *1. Formal Matters*

A. Claims 1, 3-13 and 18-24 are pending. In the Response, filed 6/19/08, to the Restriction Requirement mailed 4/18/08, Applicants elected Group I, claims 1 and 3-13. Since no traversal has been provided, Applicants' election is being treated as an election without traverse. Therefore, this Restriction is deemed proper and is made FINAL.

### *2. Claim Rejections - 35 USC § 112, second paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is confusing since it recites “the ghrelin receptor that mediates intestinal inflammation.” This implies that there is only one ghrelin receptor known, or that there is only one known which mediates intestinal inflammation. The claim becomes more confusing since it implies that there are more than one ghrelin receptor - the one expressed in the tissue and one that mediates intestinal inflammation. It is unclear if these receptors are one and the same. Claims 3-13 are rejected since they depend from claim 1.

B. Claim 1 is confusing since it is not clear how a tissue can express cells. The tissue can comprise cells expressing the receptor. Claims 3-13 are rejected since they depend from claim 1.

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### **3. Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1, 3-5 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (WO 01/87335 – reference B2 on the 1449 filed 6/19/08). The claims recite a method of inhibiting an inflammatory response in a tissue expressing ghrelin receptor positive cells by administering ghrelin. It is noted that the claims read on in vivo and do not require the subject actually has in inflammatory condition. Therefore, ghrelin administered for any reason would inherently inhibit an inflammatory response. Bryant teach (claims 1 and 5) a method of inhibiting ghrelin activity in a mammal by administering a GHS-RA (e.g. ghrelin receptor antagonist), including peptides and antibodies. The administration of the ghrelin antagonist by Bryant would inherently contact the intestinal tissue since these cells express ghrelin receptors.

Claims 10, 11 and 13 are rejected since, again, there is no requirement that a patient have inflammation, but that the inflammation would be able to be inhibited by one of the agents of claims 10 and 11 or one of the conditions in claim 13.

### **4. Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. The claim recites a method of inhibiting an inflammatory response where the agent is a soluble isoform of the ghrelin receptor, or a fragment thereof. Bryant et al. do not teach this limitation. However, they do teach numerous ghrelin receptor antagonists (claim 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used any ghrelin receptor antagonist, including those recited in instant claim 6.

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**5. Conclusion**

A. No claim is allowable.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/  
Primary Examiner, Art Unit 1647